RPP:135F US

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Molly F. Kulesz-Martin	Art Unit:	1642
Serial No:	08/811,361	Confirmation No:	1038
Filed.	March 4, 1997		
Examiner:	C. Yaen		
For:	p53as PROTEIN AND ANTIBODY THEREFOR		

I certify that this APPEAL BRIEF is being deposited on April 29, 2003 with the U.S.Postal Service as first class mail addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231

Michael I Dunn
Registration No 25,530

APPEAL BRIEF
(37 CFR 1.192)

Box AF
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicant respectfully appeals the decision of the Examiner finally rejecting Claim 11, as set forth in his Office Action dated December 31, 2002. A Notice of Appeal was timely submitted to the Patent and Trademark Office by first class mail on March 31, 2003.

Real Parties in Interest

The real party in interest is Health Research, Inc., Assignee of the above application by assignment recorded in the Patent and Trademark Office at Reel 6696, Frames 993-995 for parent application serial number 08/100,496, from which this is a divisional application.

Related Appeals and Interferences

There are no related appeals or interferences. A prior appeal was made on this application on July 24, 1998 and a decision in favor of the Applicant was rendered by the Board of Patent Appeals and Interferences on October 31, 2001 containing a new ground of rejection. The new ground of rejection was withdrawn by the Examiner and different new grounds of rejection were entered.

Status of Claims

The application originally contained one claim (Claim 11) which remains in the application. Claim 11, the only claim on appeal, is set forth in the Appendix.

Status of Amendments

Claim 11 has been amended. No amendments have been offered which have not been entered.

Summary of the Invention

The invention is a purified peptide which peptide is present in p53as protein of a mammal and is identical to the unique carboxy terminal region of p53as which distinguishes p53as protein from p53 protein. The purified peptide contains a unique epitope which is not present in p53 that distinguishes p53as protein from p53 protein. The unique epitope contains a peptide sequence selected from the group consisting of SPNC (Seq. ID #6) and SPPC (Seq. ID #7).

Issue Presented for Review

Whether Claim 11 is patentable under 35 USC 101 as having sufficient utility.

Grouping of Claims

There is only one claim.

Argument

In the last official action, the Examiner rejected Claim 11 as lacking utility under 35 U.S.C. 101. This is the only remaining rejection.

The rejection should be reversed.

The Examiner has objected to claim 11, the only pending claim, under 35U.S.C. 101 for lack of utility. With due respect to the Examiner, this rejection is completely inappropriate and should be withdrawn.

The entire specification is directed to a peptide that permits p53as to be distinguished from p53. **The claimed peptide can thus clearly be used to raise an antibody that will react with p53as but will not react with p53.** That is sufficient utility under 35 U.S.C. 101 all by itself.

Since by definition p53 and p53as differ only at the carboxy terminal sequences, any antibody that reacts with p53 will also react with p53as unless the unique claimed peptide at the p53as carboxy terminal region is used to distinguish the different p53 forms. p53 and p53as differ in at least the fact that p53as lacks the negative regulatory domain of p53 and thus one studying p53 function or using p53 species in therapy would want to know how much p53 vs. p53as is present. If there are additional differences it becomes even more important to distinguish these species. The Examiner's reliance upon "the same function as that of p53" for showing lack of utility seems misplaced. There is no doubt that p53 is different than p53as in

that p53as lacks the negative regulatory domain of p53. The claimed peptide thus has clear utility in distinguishing the two species. It is thus clear that the claimed peptide has more than enough utility to meet the requirements of 35 U.S.C. 101 in being utilizable to distinguish p53 from p53as.

The Examiner further states that "The p53as protein claimed as stated in the specification has not been clearly reported and investigated at the time of filing." The Examiner is in error in a couple of respects. The specification clearly provides support showing that the claimed peptide can be used to distinguish p53 protein from p53as protein and the Examiner admits that functions of p53 have been well studied. Further, Hupp et al. cited in the specification clearly showed that truncation of p53 at the carboxy terminal end retained p53 function but eliminated the negative regulatory domain. The truncated p53 was thus always active. p53as similarly is missing the negative regulatory domain but can otherwise be expected to have essentially the same functions as p53 because it otherwise has the same sequence as p53 up to the point of truncation shown by Hupp et al. The specification in view of Hupp et al. and data presented in the specification thus predicts that result. The Examiner's attention is, for example, called to page 7 of the specification showing correlation between cancer cell expression and p53 and p53as. There could hardly be a better utility than cancer detection. Further, if subsequently published documents verify such predictions, and they have, such documents may be considered as showing the veracity of the statements made in the specification. As a matter of law p53as thus need not have been completely studied at the time of filing, if statements made at the time of filing are subsequently verified. The Patent Office has recognized this legal principle almost

since its inception by permitting rule 132 affidavits presenting subsequent data verifying statements made in the specification.

In that regard, attention is for example called to European publication EP 0 709 397 A1 at page 2 lines 21-25. "The presence of the p53as protein in tumor cells **and antibodies for its detection** has applications in basic research on cell growth and differentiation....The association with G2 suggests a functional role in G2 arrest and potential for gene therapy using the p53as coding sequence. (emphasis added) " The entire EP publication goes on to support utility of p53as and thus the desirability of distinguishing p53as from p53. There are numerous other such publications. The rejection should be reversed.

Conclusion

In view of the foregoing, is asserted that all objections and rejections have been overcome and all claims are in condition for allowance. Reversal of the Examiner is respectfully requested.

Respectfully submitted,

Dated: April 29, 2003

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MLD/cah

Appendix

Reprinted below is the claim on appeal:

11. A purified peptide designated p53as peptide which peptide is present in p53as protein of a mammal and is identical to the unique carboxy terminal region of p53as which distinguishes p53as protein from p53 protein, said peptide containing a unique epitope which is not present in p53 said peptide containing a peptide sequence selected from the group consisting of SPNC (SEQ. ID #6) and SPPC (SEQ. ID #7).

FAX COVER SHEET

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Comments:

Enclosed are copy of already filed Appeal Brief and postcard

M Dunn